K093672

510(k) Summary of Safety and Effectiveness for: Aegis Navigation and Aegis Pelvic Application

DEC 11 2009

I. Manufacturer

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III. Product Name/Classification Name

Product Name:	Aegis Navigation Aegis Pelvic Application
Common Name:	Medical Image Processing Software System
Classification Name:	Image processing system, Class II as described in CFR 21 892.2050
Product Code:	LLZ

IV. Date Prepared

November 16, 2009

V. Device Description

Aegis Navigation and Aegis Pelvic Application products are line-extensions to Sentinelle's medical image software product Aegis. These are also referred to below as (Aegis) plug-ins.

The products are designed to assist with multi-modality (including MRI, US, SPECT, CT, PET, Fluoroscopy, Endoscopy and others) imaging and guidance of screening and interventional procedures for anatomical structures such as head and neck, thoracic, breast, abdominal and pelvis(including prostate).

Aegis Pelvic Application is a software tool intended for analyzing multi-modality images. This plug-in also identifies where and how deeply, a biopsy or localization needle should be inserted into a region of interest (including prostate and surrounding structures) to strike a target or region of interest. Registration of target anatomy with an interventional device can be performed manually or automatically based on fiducial markers. This in turn provides a calculation of the location and depth of the targeted region of interest.

Similarly, Aegis Navigation is a software tool intended for analyzing multi-modality images. This plug-in also identifies where an imaging device (e.g. an ultrasound transducer), interventional tool (e.g. a biopsy or localization needle) or other tracked instrument should be placed in order to visualize or strike a target or region of interest. In addition, Aegis Navigation provides the user with the option to view previously acquired DICOM data (e.g. MRI data) alongside of a separate imaging modality such as Ultrasound (US) or a fluoroscopic device. In the context of US, a 3-D

tracking system provides positional data regarding the transducer, which is used to guide the real-time reformatting of DICOM data to match the current US image. Interventional and imaging device operation and manipulation remains under the manual control of the trained medical professional at all times.

Additional applications of Aegis Navigation include:

- The ability to display the position of a tracked probe or instrument, overlaid on DICOM (e.g.MR or CT) data
- The ability to track the position of an US transducer as it collects data, then retrospectively display reformatted DICOM (e.g. MR/CT) data slices oriented to match the previously acquired ultrasound images.

VI. Intended Use

This device provides two and three-dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. Supported imaging modalities include Magnetic Resonance (MR), Ultrasound (US), Single Photon Emission Computed Tomography (SPECT), Computed Tomography (CT), Positron Emission Tomography (PET), Fluoroscopy and Endoscopy. Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices.

This device provides the capability to overlay annotations on 2D or 3D medical image displays. These annotations may represent the position of instruments including but not limited to biopsy needles, guidance wires, imaging probes or other tracked devices.

This device is intended to assist skilled medical professionals in clinical screening and interventions, for anatomical structures where imaging is currently used for visualizing such structures, including head and neck, breast, thoracic, and abdominal applications (including pelvis).

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 MPixel resolution and meets other technical specifications reviewed and accepted by the FDA.

VII. Substantial Equivalence

Sentinelle's Aegis Navigation and Aegis Pelvic Application are substantially equivalent to:

Device Name:	**Eigen 3D-Imaging Workstation**
Manufacturer:	Eigen LLC
510(k) Number:	K081093
Decision Date:	May 1, 2008
Decision:	Substantially Equivalent

Device Name:	**Aegis**
Manufacturer:	Sentinelle Medical Inc.
510(k) Number:	K070244
Decision Date:	February 9, 2007
Decision:	Substantially Equivalent

Device Name:	**Abaris**
Manufacturer:	Traxtal Inc.
510(k) Number:	K053610

Decision Date:	April 19, 2006
Decision:	Substantially Equivalent

Sentinelle's Aegis Navigation and Aegis Pelvic Application are software plug-ins for use in conjunction with our legally marketed device, Sentinelle Aegis [K070244]. As such, Aegis Navigation and Aegis Pelvic Application inherit much of their functionality from the approved device.

Table 2 lists the technological characteristics, as derived from the Indications for Use and the Device Description of Aegis Navigation and Aegis Pelvic relative to the Sentinelle Aegis, Eigen 3D-Imaging Workstation and Traxtal Abaris predicate devices. The technological characteristics of Aegis Navigation and Aegis Pelvic Applications are the same or equivalent to those found in the predicate devices, as demonstrated in Table 2 below.

A high level summary of the comparison is as follows:

1) From the Aegis predicate to the current submission, clinical screening and interventional capabilities are extended to include any anatomical structures where imaging is currently used for visualizing such structures. All of the visualization, analysis, measurement and display functionality employed are equivalent to the Aegis predicate device so no new issues of safety and effectiveness arise for screening. For interventional guidance, registration of MR image DICOM coordinates to physical patient coordinates is done using the same functionality as the Aegis predicate. This, combined with the conducted test results show that the software is accurate and functions as specified, and no new issues of safety and effectiveness arise.
2) From the Aegis predicate to the current submission, Aegis Navigation adds the ability to manipulate image display based on tracked data acquired from 3D positioning devices. The interface to the positional tracking device is accomplished in the same manner as the Abaris predicate, and the registration of spatially tracked instruments to coordinates in the image space is accomplished in the same manner as the Abaris and Eigen predicates. This, combined with the conducted registration and targeting tests of Aegis Navigation show that spatial tracking functionality is accurate, functions as specified, and no new issues of safety and effectiveness arise.

The device labeling includes the Operator's Guide (User Manual) which includes indications for use, cautions, warnings, contraindications and instructions. This information assures safe and effective use of the device.

VIII. Testing and Performance Data

Testing for Aegis Navigation and Aegis Pelvic Application was performed to ensure that all functional requirements have been met, and that core functions execute as expected. Testing was conducted in-house by trained personnel in a simulated work-environment using phantoms or volunteers to obtain the functional and accuracy test results.

Registration accuracy tests were performed to ensure that the registration and correspondence between MR and ultrasound meets or exceeds specified criteria. Needle verification tests were also performed to ensure that needle registration and targeting results met or exceeded specified criteria. The test methodology employed was identical to that of the Aegis predicate device, conducted by targeting locations within a phantom and confirming that the selected target location/needle location based on the registration calculation is within the same tolerance range or better than the Aegis predicate device. The completed test procedures and results are presented in the following appendices:

Appendix Z1a – Navigation Software Verification Specifications [SMI-0997]
Appendix Z1b- Navigation Software Verification Results [SMI-0337]
Appendix Z1c – Navigation System Accuracy Specifications [SMI-0258]
Appendix Z1d – Navigation System Accuracy Test Results [TR-0326]
Appendix Z2a & Z2b – Pelvic Software Verification Specifications including Accuracy [SMI-917]
Appendix Z2c - Pelvic Software Verification Results including Accuracy [SMI-1059]

Aegis Navigation and Aegis Pelvic Application's indications for use are a combination of the indications for use of three legally marketed predicate devices: Sentinelle's Aegis, Traxtal's Abaris and Eigen's 3D-Imaging Workstation. Aegis Navigation and Aegis Pelvic Application combine the features of these predicate devices and do not provide novel functionality.

As such, the features provided by Aegis Navigation and Aegis Pelvic Application do not in themselves raise new concerns of safety or effectiveness.

Test Conclusion

The results of these tests demonstrate that the system accuracy is within specification and performs as well as, or better than Aegis, the legally marketed predicate device. Comparison to the other predicate devices is not directly possible since the testing methodology and accuracy specifications are not publicly available. Over two years of extensive clinical use of the Aegis predicate device shows that the specified accuracy and the accuracy testing methodology of the Aegis predicate provide safe and effective targeting of instruments to image-identified target locations.

As such, Aegis Navigation and Pelvic Application software plug-ins are as safe and effective as the predicate devices and are substantially equivalent to existing products on the market today. The software performs as well as, or better than legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Sentinelle Medical, Inc.
% Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

DEC 11 2009

Re: K093672
Trade/Device Name: Sentinelle Aegis Navigation & Sentinelle Aegis Pelvic Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 25, 2009
Received: November 27, 2009

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication(s) For Use

510(k) Number: K093672

Device Name: Sentinelle Aegis Navigation & Sentinelle Aegis Pelvic Application

Indications for Use:

This device provides two and three-dimensional image review, manipulation, and analysis tools to assist users in screening, diagnosis, planning and performing image-guided interventional procedures. Supported imaging modalities include Magnetic Resonance (MR), Ultrasound (US), Single Photon Emission Computed Tomography (SPECT), Computed Tomography (CT), Positron Emission Tomography (PET), Fluoroscopy and Endoscopy. Images and data are received from various imaging systems and other sources such as calibrated spatial positioning devices.

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Prescription Use (Part 21 CFR 801 Subpart D): __√__ **AND/OR** Over-The-Counter Use (Part 21 CFR 801 Subpart C) ____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K093672